Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of the efficacy of repeated gonadotropin-releasing hormone agonist (GnRH-a) versus adding low dose human chorionic gonadotropin (HCG) for ovulation induction in patients with polycystic ovary syndrome undergoing IVF/ICSI

Protocol summary

Study aim

Assessment of the efficacy of repeated gonadotropin-releasing hormone agonist (GnRH-a) versus adding low dose human chorionic gonadotropin (HCG) for ovulation induction in patients with polycystic ovary syndrome undergoing IVF/ICSI

Design

This study is designed as a randomized, phase 3 clinical trial with parallel groups, and a sample size of 60 participants. The randomization method will be the block randomization method.

Settings and conduct

This RCT will be conducted at Arash women's Hospital on women with infertility and PCOS. Eligible patients will be divided into two groups after obtaining informed consent. A transvaginal ultrasound will be performed on the second or third day of the menstrual cycle. Ovulation induction will be performed using the rFSH drug at a dose of 150-225 units. After 5 days, if the dominant follicle size is more than 12 mm, 0.25 mg GnRH antagonist will be injected every day. Follicle growth will be monitored by vaginal ultrasound. triggering will be performed if there are at least three dominant follicles (>=17 mm). Type of triggering depends on whether the patient is in group A or B. Both groups will undergo oocyte pick up 34 to 36 hr later. Due to the patient's knowledge of the type of intervention performed, it is not possible to blind the patient.

Participants/Inclusion and exclusion criteria

Infertile women with PCOS who are aged 18-38 years old and have normal BMI, normal uterine cavity will be included. History of repeated implantation failure, Endocrinopathies, intaking OCP, and use of TESE or PESA are the exclusion criteria.

Intervention groups

Group A: Subcutaneous injection of 0.2mg Decapeptyl ampoule (GnRH-a) that will be repeated with a half-dose after 12 hr Group B: Subcutaneous injection of 0.2 mg Decapeptyl ampoule (GnRH-a) with 2000 units of HCG ampoule

Main outcome variables

Rate of OHSS, number of oocytes, M II oocytes, and embryos

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110731007165N8**
Registration date: **2019-12-19, 1398/09/28**
Registration timing: **prospective**

Last update: **2019-12-19, 1398/09/28**
Update count: **0**

Registration date

2019-12-19, 1398/09/28

Registrant information

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Ladan Kashani
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2019-12-31, 1398/10/10
Expected recruitment end date
2021-02-19, 1399/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of repeated gonadotropin-releasing hormone agonist (GnRH-a) versus adding low dose human chorionic gonadotropin (HCG) for ovulation induction in patients with polycystic ovary syndrome undergoing IVF/ICSI

Public title
repeated gonadotropin-releasing hormone agonist (GnRH-a) versus low dose human chorionic gonadotropin (HCG)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Aged between 18-38 years old Body mass index below 30 and above 19 kg/m2 Normal uterine cavity Ovulation induction by GnRH antagonist cycle regimen
Exclusion criteria:
Repeated implantation failure WHO 1 group Using Percutaneous Epididymal Sperm Aspiration (PESA) or testicular sperm extraction (TESE) History of taking oral contraceptive pills for more than three months before the IVF Endocrinopathies
Age
From **18 years** old to **38 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The statistician will divide eligible participants into two groups by using block randomization method. The size of the blocks in this study will be six. The randomization tool used in this study is sealed envelopes that will be prepared by the statistician.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Qods St, Keshavarz Blvd, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2019-09-02, 1398/06/11
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1398.493

Health conditions studied

1

Description of health condition studied
Infertility associated with polycystic ovarian syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Ovarian hyperstimulation syndrome (OHSS)
Timepoint
At the end of the study
Method of measurement
Hospital records

2

Description
Metaphase II (MII) oocytes
Timepoint
At the end of the study
Method of measurement
Hospital records

3

Description
Total Number of oocytes
Timepoint
At the end of the study

Method of measurement
Hospital records

4

Description
Number of embryos
Timepoint
At the end of the study
Method of measurement
Hospital records

Secondary outcomes

1

Description
Endometrial thickness
Timepoint
At the time of embryo transfer
Method of measurement
Vaginal Ultrasound

2

Description
Embryos quality
Timepoint
At the end of the study
Method of measurement
Hospital records

Intervention groups

1

Description
First Intervention group (Group A): Subcutaneous injection of 0.2mg Decapeptyl ampoule (GnRH-a) that will be repeated with a half-dose after 12 hr
Category
Treatment - Drugs

2

Description
Second Intervention group (Group B): Subcutaneous injection of 0.2 mg Decapeptyl ampoule (GnRH-a) with 2000 units of HCG ampoule
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash women's hospital
Full name of responsible person
Dr.Ladan Kashani
Street address
No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Web page address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Arash Women 's Hospital

Full name of responsible person
Dr. Mahdiyeh Sadat Portabatabaei

Position
Obstetrics and Gynecology Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available